Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 106 1
Rockville, MD 20852

(017 '99 DEC -7 A10:24

To Whom It May Concern:

December 1, 1999

I wish to comment on the proposed FDA regulation to regulate certain bone allograft material as a medical device. I currently use a large amount of cadaver derived allograft material in spinal fusions and anticipate this need to continue. I am somewhat surprised at the proposed regulation to treat this material as a "device" rather than, or in addition to, "tissue". Where do we draw the line between a "device" and "tissue"? I routinely use many patient's own bone (autograft) for fusion. After I fashion it to "fit" is it then a "device" too?

I think the current regulations regarding the safety of bone allograft are adequate to provide safety to the public with regards to disease transmission, The FDA has no business telling me or determining HOW I choose to best use these products after they are fashioned by me or anyone else to fit a particular setting. The nature of the material does not change. Various uses of these products are simply dictated by the shape and/or size of the graft required for certain settings and does not change the inherent nature of the product.

Once again, these are NOT devices, but tissue. Any interference that would result in decreased supply in an already tight market would be deleterious to the public if these grafts were to become more scarce than they already are.

Thank you for your consideration of my opinion an if you would like further comment or if I an assist you in any way, please call.

Sincerely,

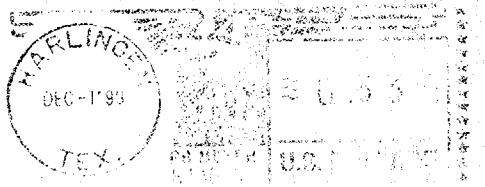
Brent L. Clyde

Brent L. Clyde, M.D.

97N-4845

C39

DRS. FENNEGAN & SIX
NEIJROSURGLCAL ASSOCIATES
1725 Ed Carey Drive
Harlingen, Texas 78550



Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

20837=0001